approximately 3 hours to run a report that satisfies the act's requirements. For sponsors of approved applications that are inactive (i.e., the approved drug is not being marketed), the sponsor would only have to submit a report stating that the drug is not being marketed, which FDA estimates will take approximately 1 hour.

FDA has developed a form to report the information required by section 512(l)(3) of the act. FDA plans to make the form available to animal drug manufacturers through FDA's website however, use of the form would be entirely voluntary. The form contains various fields for information, including the drug manufacturer's name, new animal drug approval number, active ingredient name, National Drug Code number, container size, potency, and the number of units sold by month.

The animal drug manufacturers can meet the statutory requirements by submitting their information in paper format using the FDA-provided form, one of their own designs, or by designing their own electronic form whose results could be submitted to the agency on a compact disc or on paper. The cost to animal drug sponsors for gathering the necessary information for report design and preparation or for completing FDA's form in the first year of reporting is $107,880 (29 active sponsors times 80 hours times $46.50 per hour = $107,880). This is a one-time cost for a computer or mathematic employees to design and prepare a report that satisfies the statutory requirements of section 512(l)(3) of the act.[1] For subsequent years, the preparation of the report should take approximately 3 hours. Thus, the total cost in subsequent years would be $139.50.

Regarding the recordkeeping burden associated with this collection of information, FDA believes that most of the necessary information for the annual report required to be submitted under section 512(l)(3) of the act is already collected and maintained by animal drug manufacturers under existing requirements.

Animal drug manufacturers are already required to maintain distribution records for their drug products to comply with FDA's current good manufacturing practice regulations under § 211.196 (21 CFR § 211.96) (OMB Control No. 0910–0139), and to comply with regulations for periodic drug experience reports under § 514.80(b)(4)(i) (21 CFR § 514.80(b)(4)(i)) (OMB Control No. 0910–0284) of FDA regulations. Therefore, FDA believes that manufacturers of animal drugs already possess the computers, software, and additional equipment necessary to collect and maintain the necessary records, and to make reports.

Section 512(l)(3) of the act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. Under § 211.196 (OMB Control No. 0910–0139), manufacturers currently are required to maintain distribution records that include the dosage form and date the drug is distributed. Additionally, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of their usual and customary practice. However, FDA estimates additional hourly burden required by section 512(l)(3) of the Act as shown in table 2 of this document.

Dated: October 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25671 Filed 10–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Parent-Child Assistance Program (P–CAP) in the Fetal Alcohol Spectrum Disorder (FASD) Center of Excellence—New

Since 2001, SAMHSA's Center for Substance Abuse Prevention has been operating a Fetal Alcohol Spectrum Disorder (FASD) Center of Excellence which addresses FASD mainly by providing trainings and technical assistance; and developing and supporting systems of care that respond to FASD using effective evidence based practices and interventions.

Currently the integration of evidence-based practices into service delivery organizations is being accomplished through subcontracts. One such intervention which integrates prevention strategies into service delivery organizations is the Parent-Child Assistance Program (P–CAP) targeting pregnant or postpartum women. The P–CAP program uses the following 11 data collection tools.

DESCRIPTION OF INSTRUMENTS/ACTIVITY FOR PARENT-CHILD ASSISTANCE PROGRAM (P–CAP)

Instrument/Activity	Description
At Baseline/Enrollment:	
CRSQ	The Community Referral Screening Questionnaire (CRSQ) is a screening form administered to individuals referred to P–CAP. The purpose of the form is to determine eligibility for enrollment in P–CAP.
ASI—Part A	The Addiction Severity Index (ASI) Part A is an intake interview administered at client enrollment. The ASI Part A includes questions about past 30-day alcohol use, lifetime use, age at first use, month and year of last use, range of use (T–ACE), and use during pregnancy, thereby providing a thorough assessment of alcohol consumption.
ASI—Part B & Twin	The Addiction Severity Index (ASI) Part B is an intake interview administered as soon as possible after the target child birth. The ASI Part B includes questions about the target child at birth and alcohol use during the pregnancy. If the target birth is of twins then the Twins Addendum form is administered.

[1] BLS Occupation Employment and Wages, May 2006, by occupation, for all industries (*http://www.bls.gov*). Wage ($46.50) includes mean hourly wage of $33.22 for Standard Occupational Classification 15–0000, computer and mathematics occupations, all industries; we add 40 percent to account for benefits.

DESCRIPTION OF INSTRUMENTS/ACTIVITY FOR PARENT-CHILD ASSISTANCE PROGRAM (P–CAP)—Continued

Instrument/Activity	Description
Demographic Data	The Demographic Questionnaire is administered after client enrollment. The questionnaire includes race, educational attainment, marital status, and an alcohol assessment.
Process Monitoring:	
Weekly Advocate Time Summary	The P–CAP Weekly Advocate Time Summary Sheet is administered on a weekly basis. The form tracks time spent on the phone, in person, or providing transportation to each client.
Monthly Updates	The Monthly Update form is administered on a monthly basis. The form records any changes in drug and alcohol use, pregnancy, child custody, and sources of income.
Biannual Documentation of Progress (every 6 months).	The Biannual Documentation of Progress is administered every six months. The form documents changes in alcohol/drug treatment, abstinence from alcohol/drugs, birth control and pregnancy, connection to other services, and family stability and client activity.
At Exit:	
Exit ASI	The Exit ASI Follow-Up is administered at the end of the program, at 36 months. The Exit ASI uses a format that is identical to the Addiction Severity Index administered at intake, providing pre- and post-test data for the intervention.
Client Exit Close Out Form	The Client Exit Close-Out Form documents the total number of months the client spent in P–CAP, number of different advocates who worked with the client, and whether the client ever moved out of the area while enrolled in P–CAP.
Ad hoc:	
Advocate Accounting of Tracing Activity on Missing Post-Exit Client.	The Advocate Accounting of Tracing Activity on Missing Post-Exit Client is used to track activity to locate a missing client. When a client is missing, the form is to be completed each month, instead of the Monthly Update form, until the missing post-exit client is brought in for an Exit Interview.
Lost Post-Exit Client Form	The Lost Post-Exit Client Form is used when the client is at least six months past her three-year exit date in the program and has not completed the ASI exit interview. The form documents the reason the client has not completed the ASI exit interview.

Two P–CAP subcontracts were awarded in February 2008. P–CAP uses an intensive paraprofessional home visitation model to reduce risk behaviors in pregnant women with substance abuse problems. The primary goal of P–CAP is to prevent future births of alcohol and drug exposed children to women who are at risk. The program uses a holistic case management approach, which is a complement to traditional substance abuse treatment. In addition to addressing alcohol and drug use, the program also aims at reducing other risk behaviors and addressing the health and social well being of mothers and their children.

At the initial client visit, the women receive a comprehensive assessment which includes an assessment for alcohol consumption, contraception use, and use of community services. At-risk women receive case management and every 4 months women are re-evaluated to determine their clinical goals. Counselors complete ''Documentation of Client Progress'' form every 6 months and a final ''Documentation of Client Progress'' at 36 months. In addition, the counselors complete a weekly advocate time sheet, summarizing their activities within the program. All forms are completed online using the web-portal. All participating subcontractors will maintain identifiable information on clients for service delivery purposes but no identifiable information will be transmitted to SAMHSA.

The data collection is designed to evaluate the implementation of P–CAP by measuring whether abstinence from alcohol is achieved and risk for alcohol-exposed births is eliminated.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument/Activity	Number of respondents	Number of responses per respondent	Total number of responses	Average burden per response	Total burden hours collection
At Baseline/Enrollment:					
CRSQ	190	1	190	0.08	15
ASI—Part A	190	1	190	2.75	523
ASI—Part B & Twin	190	1	190	0.25	48
Demographic Data	190	1	190	0.08	15
Process Monitoring:					
Weekly Advocate Time Summary	190	52	9,880	0.50	4,940
Intermediate Outcomes:					
Monthly Updates	190	12	2,280	0.50	1,140
Biannual Documentation of Progress (every 6 months)	161	2	322	0.33	106
At Exit:					
Exit ASI	190	1	190	2.25	428
Client Exit Close Out Form	161	1	161	0.25	40
Ad hoc:					
Advocate Accounting of Tracing Activity on Missing Post-Exit Client	29	1	29	0.25	7
Lost Post-Exit Client Form	29	1	29	0.25	7
Total	190		13,651		7,269

Written comments and recommendations concerning the proposed information collection should be sent by November 25, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: October 19, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–25667 Filed 10–23–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0496]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Standard for Flavored Cigarettes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed extension of an existing collection of information pertaining to the tobacco product standard for flavored cigarettes under the Family Smoking Prevention and Tobacco Control Act (FSPTCA).

DATES: Submit written or electronic comments on the collection of information by December 28, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, *Jonnalynn.Capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed extension of an existing collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Tobacco Product Standard on Flavored Cigarettes (OMB Control Number 0910–0647—Extension)

On June 22, 2009, the President signed the FSPTCA (Public Law 111–31) into law. The FSPTCA amended the Federal Food, Drug, and Cosmetic Act (FDCA) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

FDA is requesting an extension of an existing collection of information pertaining to section 907(a)(1)(A) of the FDCA, as amended by the FSPTCA, which provides a general tobacco standard special rule for cigarettes that became effective on September 22, 2009. This special rule for cigarettes states in part that: ''* * * a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.''

As part of our enforcement strategy, FDA created a Tobacco Call Center (with a toll-free number) to accept information from the public about violations of this provision, known as the cigarette flavor ban. Callers are able to report violations of the cigarette flavor ban and FDA will determine whether to conduct targeted followup investigations based on information the agency receives. Members of the public who wish to report a violation will be asked for certain information: Name and contact information, which are optional, date that the caller observed or purchased the alleged violative product, description of the tobacco product, and address of the retail outlet or Internet address where the violative product was available. FDA developed a form (FDA Form 3734) that Call Center representatives use to record this information. Additionally, this form is posted on FDA's Internet (*http://www.accessdata.fda.gov/scripts/email/TobaccoProducts/flavoredCigarettes.cfm*), which allows the public to report violations of the cigarette flavor ban by filling out the form on-line. Others may simply choose to send a letter to FDA. (Information about how to contact FDA's Center for Tobacco Products is posted at *http://www.fda.gov/TobaccoProducts/default.htm*). FDA described how to report information about possible violations in a **Federal Register** notice reminding regulated industry of the effective date of the ban on certain flavored cigarettes (September 25, 2009; 74 FR 48974). FDA also included this information in the following outreach materials:

- Letter to our tobacco control partners announcing the cigarette flavor ban and soliciting information on possible violations,